510(k) Summary

JUN 15 2000

510(k) Summary.

This summary of 510(k) is submitted in accordance with the requirements of the Safe Medical Devices act of 1990 and 21 C.F.R. §807.92.

Submitters Name: Milex Products, Inc.
4311 North Normandy Ave.,
Chicago, IL 60634
Registration Number: 1413139
Contact Person: Ms. Cara Furlong (Quality Assurance Manager)
Telephone Number: 773-736-5500

Summary Prepared: 06/05/00

ETO Processing Site: Chicago Sterilization Services
2601 South Archer Avenue,
Chicago, IL 60608
FDA Establishment Number: 1422474

Device Name: 3mm Soft (yellow) Pipet Curet

Classification: According to §513 of the Federal Food, Drug & Cosmetic Cat, the device classification is Class II, Performance Standards (21 C.F.R. §884.1175).

Predicate Device: Pipet Curet (3mm & 4mm) [Endometrial Suction Curette]
Marketed by:
Milex Products, Inc.
Chicago, IL 60634

Product Description:
The proposed Milex 3mm Soft (yellow) Pipet Curet, consists of a polypropylene curette with a closed distal end and a curette opening. The stylette is made from polyethylene with a food grade yellow pigment to distinguish it from the more rigid models in the product family.
Suction is created by rapid, uninterrupted withdrawal of an enclosed stylette. A double o-ring at the distal end of the stylette ensures the tight fit necessary to create negative pressure.

Indications for Use:
The intended use of 3mm Soft (yellow) Pipet Curette is the same as Pipet Curet (3mm & 4mm) – predicate device. It is a single use, sterile, disposable endometrial sampling device designed to be used for histologic evaluation of uterine mucosal lining. The specimens obtained are then used for the following:

- Cancer screening
- Endometrial dating
- Determine response to estrogen replacement therapy
- Bacterial culturing
- Detection of pathology resulting in infertility
- Monitoring patients receiving Tamoxifen Therapy
- Secondary amenorrhea

Technological Characteristics of the 3mm Soft (yellow) Pipet Curet Vs. Technological Characteristics of the 3mm Pipet Curet –Predicate.

The technological characteristics of the 3mm Soft (yellow) Pipet Curet varies from that of the 3mm Pipet Curet in its flexability and the color pigment. (The color pigment has been added to distinguish it from the predicate 3mm Pipet Curet). The added flexibility is achieved by the use of a polyethylene stylette as opposed to a Nylon stylette.

The overall function, safety and efficacy of the new device [3mm soft(yellow) Pipet Curet] remains unchanged from that of the 3mm Pipet Curet.

Non-Clinical Performance:

The Flexibility of the new device was tested against that of the existing model. Results confirm the new device is more flexible than the existing model.

The size of the Curette Opening (port size) was compared between the two models (3mm soft (yellow) PC Vs 3mm PC). Data confirms that the size of the curette opening is uniform between the two models.

Biocompatibility Studies - Sensitization, Cytotoxicity and irritation studies have been set up by a contracted laboratory. Results will be made available for review by the FDA upon completion.

A laboratory has been contracted to perform leaching Studies. Results will be made available for review by the FDA upon completion (Due 06/13/00).

Conclusions:

The Intended use, function and technical characteristics along with results obtained from the non-clinical tests performed indicate that the new device. The 3mm Soft (yellow) is substantially equivalent in safety, effectiveness and performance to predicate device, the 3mm Pipet Curet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2000

Ms. Cara Furlong
Quality Assurance Manager
Milex Products, Inc.
4311 North Normandy Avenue
Chicago, IL 60634

Re: K001545
Pipet Curet
Dated: April 25, 2000
Received: May 18, 2000
Regulatory Class: II
21 CFR §884.1175/Procode: 85 HHK

Dear Ms. Furlong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

FDA
Document Mail Center, Dept HZF - 401
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

May 26, 2000

Request for Special 510(k): Device Modification

510(k) Number: K001545

Device Name: Pipet Curet

"Indication for Use":

- Cancer Screening
- Endometrial dating
- Determine response to estrogen replacement therapy
- Bacterial culturing
- Detection of pathology resulting in infertility
- Monitoring patients receiving Tamoxifen Therapy
- Secondary Amenorrhea

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format)

David A. Bogan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001545